

United States Senate

WASHINGTON, DC 20510

August 16, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Sharpless,

We write today to request that the Food and Drug Administration (FDA) work to facilitate access to over-the-counter (OTC) contraceptives. We suggest that FDA work with manufacturers to provide greater regulatory certainty and a streamlined pathway for prescription birth control to be available over-the-counter, similar to FDA's actions related to improving access to naloxone, a treatment for opioid overdoses.

In January 2019, the FDA announced a plan to spur development of OTC naloxone by coordinating pre-approved consumer friendly labeling and streamlining regulatory pathways. Medical experts have long recognized the safety and efficacy of naloxone as an opioid overdose treatment; however, regulatory barriers in the prescription-to-over-the-counter switch (Rx-to-OTC switch) process have prevented improved access.

We applaud the FDA for taking these groundbreaking steps to combat the opioid epidemic, and urge that these tools also be used to encourage the development of OTC contraceptives.

Despite medical providers strongly advocating for OTC contraceptive access, existing burdensome regulatory processes deter manufacturers from undertaking the arduous process to conduct the additional clinical studies and develop an Rx-to-OTC switch product.

We recognize the public health benefits of providing greater access and choice for American families to contraceptives. For many women across the country, the added strain from a prescription requirement means hours lost from work or their personal lives and increased stress. While some states have undertaken steps to increase access at the pharmacy counter, those efforts fall short of meaningful, widespread adoption of OTC contraceptive availability.

We encourage the FDA to work with manufacturers to increase convenient access to oral contraceptives that have long been determined to be safe and effective. We will continue to advocate in the Senate for passage of our legislation, S. 930, the Allowing Greater Access to Safe and Effective Contraception Act, which incentivizes manufacturers to go through the OTC approval process.

We call upon the FDA to use its existing authorities and regulatory tools to promote a framework that encourages development of OTC contraceptives and recognizes the public health benefits of increasing access to OTC contraceptives for women and families across the country.

Sincerely,



Cory Gardner
United States Senator



Joni K. Ernst
United States Senator